AUG - 1 2003

SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **K031532**

Applicant information:

Date Prepared:	May 12, 2003
Name:	Metro Optics of Austin, Ltd.
Address	15802 Vision Drive Pflugerville, TX 78660
Contact Person:	Mr. Steve Webb Vice President
Phone Number:	(512) 251-2382
Fax:	(512) 251-6554
Official Correspondent:	Med-Vice Consulting, Inc.
Regulatory Consultant:	Ms. Deanna Werber or Mr. Martin Dalsing 623 Glacier Drive Grand Junction, CO 81503
Phone Number:	(970) 243-5490
Fax Number:	(970) 243 -5501

Device Information:

Regulatory Classification:	Class II
Product Code:	LPL
Trade Name:	SatureEyes II (acofilcon A), (acofilcon B) & (tetrafilcon A) Lens for Daily Wear (clear and blue visibility-handling tint, lathe-cut)
Purpose for 510(k)	Addition of Material to an already cleared device
Classification Name:	Lenses, Contact (other material), Daily Wear

Purpose of 510(k) submission:

ADDITION OF MATERIALS TO AN ALREADY CLEARED DEVICE ~

Metro Optics of Austin, Inc. proposes to manufacture the SatureEyes II (acofilcon A), (acofilcon B) & (tetrafilcon A) Soft Contact Lens for Daily Wear. Data supporting substantial equivalency to the predicate devices, performance, and safety and efficacy of the (acofilcon A), (acofilcon B) & (tetrafilcon A) polymer is contained in this submission.

Equivalent Devices:

The SatureEyes II (acofilcon A), (acofilcon B) & (tetrafilcon A) Soft Contact Lens for Daily Wear is substantially equivalent to the predicate device identified below in terms of intended use and design.

Predicate device manufacturer:
Metro Optics of Austin, Ltd.
15802 Vision Drive
Pflugerville, TX 78660

Device name:
Metro-G 55 (5X) (hioxifilcon A) Spherical & Toric
510(k) #: K953199

Metro-G 3X (hioxifilcon B) Spherical & Toric Soft Contact Lenses for Daily Wear
510(k) # K964902

MetroFocal Toric Multifocal (hioxifilcon A) Soft Daily Wear Contact Lens
510(k) #: K001584

Device Description:

The SatureEyes II Soft Contact Lens for Daily Wear is fabricated from (acofilcon A), (acofilcon B) or (tetrafilcon A), which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The (acofilcon A), (acofilcon B) & (tetrafilcon A) soft hydrophilic contact lens has a spherical back surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped however, it will return to its proper configuration when completely re-hydrated in the proper storage solution.

The non-ionic lens material, **(acofilcon A)**, is a terpolymer based on high purity Glycerol Methacrylate2,3-Dihydroxypropyl Methacrylate (GMA), with N-vinyl-2 pyrrolidone (NVP), methyl methacrylate (MMA), and 2-hydroxyethyl methacrylate (2-HEMA) and crossed-linked with Diallyl Maleate (DAM). It consists of 42% acofilcon A and 58% water by weight when immersed in normal saline solution buffered with sodium bicarbonate. The lenses are available in clear and with a blue visibility-handling tint, Color additive 'Reactive Blue 4'.
The physical properties of the **(acofilcon A)** lens are:

Refractive Index	1.40 (hydrated)
Light Transmission (clear)	greater than 95% T
Light Transmission (tinted)	greater than 95% T
Water Content	58 %
Specific Gravity	1.103 (hydrated)
Oxygen Permeability	25.50 X 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C), (revised Fatt method).

The non-ionic lens material, **(acofilcon B)**, is a terpolymer based on high purity Glycerol Methacrylate2,3-Dihydroxypropyl Methacrylate (GMA), with N-vinyl-2 pyrrolidone (NVP), methyl methacrylate (MMA), and 2-hydroxyethyl methacrylate (2-HEMA) and crossed-linked with Diallyl Maleate (DAM). It consists of 51% acofilcon B and 49% water by weight when immersed in normal saline solution buffered with sodium bicarbonate. The lenses are available in clear and with a blue visibility-handling tint, Color additive 'Reactive Blue 4'.

The physical properties of the **(acofilcon B)** lens are:

Refractive Index	1.42 (hydrated)
Light Transmission (clear)	greater than 95% T
Light Transmission (tinted)	greater than 95% T
Water Content	49 %
Specific Gravity	1.142 (hydrated)
Oxygen Permeability	15.8 X 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C), (revised Fatt method).

The non-ionic lens material, **(tetrafilcon A)**, is a random terpolymer of 2-hydroxyethyl methacrylate, N-vinyl-pyrrolidone (NVP), methylmethacrylate (MMA), in a three dimensional network of terpolymer chains by divinylbenzene cross links. It consists of 58% (tetrafilcon A) and 42% water by weight when immersed in normal saline solution buffered with sodium bicarbonate. The lenses are available in clear and with a blue visibility-handling tint, Color additive 'Reactive Blue 163'.

The physical properties of the **(tetrafilcon A)** lens are:

Refractive Index	1.43 (hydrated)
Light Transmission (clear)	greater than 93% T
Light Transmission (tinted)	greater than 95% T
Water Content	42 %
Specific Gravity	1.12 (hydrated)
Oxygen Permeability	9.3 X 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C), (revised Fatt method).

Pre-Clinical Performance Data:
Pre-clinical performance data addressing the cytotoxicity test, systemic injection test, and ocular eye irritation test can be referenced in Contamac Ltd.'s 510(k)s K023349 & K024045 and CooperVisions 510(k) K954139.

(Reference Permission to Reference letters appendix D of submission)

Intended Use:

The **SatureEyes II (acofilcon A), (acofilcon B) Spherical** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity.

The **SatureEyes II (acofilcon A), (acofilcon B) Toric** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes with myopia or hyperopia and may have astigmatism of 10.00 diopters or less where the astigmatism does not interfere with visual acuity.

The **SatureEyes II (acofilcon A), (acofilcon B) Multifocal** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes with myopia or hyperopia and are presbyopic.

The **SatureEyes II (acofilcon A), (acofilcon B) Toric Multifocal** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes with myopia or hyperopia, have astigmatism of .10.00 diopters or less and are presbyopic.

Eyecare practitioners may prescribe the lens for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system.

Substantial Equivalence:

The new device will be manufactured according to specified process controls and a Quality Management System certified to QSR guidelines. The new device will undergo manufacturing, packaging and sterilization procedures similar to devices currently marketed and distributed by Metro Optics of Austin, Inc. Being similar with respect to indications for use, materials, physical construction and safety & effectiveness to the predicate devices, this meets the requirements per section 510(k) of the act regarding substantial equivalence and *does not raise* different questions of safety and effectiveness than the predicate devices identified above.

The following table illustrates that the Intended Use, Indications, Production method, and design, of the SatureEyes II (acofilcon A), (acofilcon B) & (tetrafilcon A) Soft Contact Lens for Daily Wear is substantially equivalent to the predicate devices. In addition, the water content, material, polymer, dK value, and light transmission are as well substantially equivalent to the predicate devices.

	CHARACTERISTICS	New Device SatureEyes II	Predicate Device *MetroFocal Toric	Predicate Device *Metro-G 55 (5X) *Metro-G (3X)
1.)	INTENDED USE	Daily wear, Soft Contact Lens	Daily wear, Soft Contact Lens	Daily wear, Soft Contact Lens
2.)	INDICATION	The SatureEyes II (acofilcon A), (acofilcon B) & (tetrafilcon A) Soft Contact Lenses for Daily Wear (clear and blue visibility-handling tint, lathe-cut)are indicated for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10 diopters and may be presbyopic. The lens is available clear and with a blue visibility-handling tint.	*MetroFocal Toric (hioxifilcon A) Soft Multifocal) Daily Wear Contact Lenses are indicated for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10 diopters and may be presbyopic. The lens is available clear and with a blue visibility-handling tint.	*Metro-G 55 (5X) (hioxifilcon A) *Metro-G (3X) (hioxifilcon B) Spherical and Toric Soft Contact Lenses for Daily Wear are indicated for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 4.50 diopters. The lens is available clear and with a blue visibility-handling tint.
3.)	PRODUCTION METHOD	Lathe-Cut	Lathe-Cut	Lathe-Cut
4.)	DESIGN	spherical, toric, multifocal toric multifocal	multifocal toric multifocal	spherical, toric,
5.)	HYDROPHILLIC MATERIAL/ USAN	(acofilcon A) (acofilcon B) (tetrafilcon A)	(hioxifilcon A)	(hioxifilcon A) (hioxifilcon B)
a.	Water Content	(acofilcon A) - 58% (acofilcon B) - 49% (tetrafilcon A) - 43%	(hioxifilcon A) - 58%	(hioxifilcon A) - 58% (hioxifilcon B) - 48%
b.	Specific Gravity	(acofilcon A) - 1.103 (hydrated) (acofilcon B) - 1.142 (hydrated) (tetrafilcon A) - 1.12 (hydrated)	(hioxifilcon A) - 1.18 hydrated	(hioxifilcon A) - 1.18 hydrated (hioxifilcon B) - 1.142 hydrated
c.	Oxygen Permeability * Revised FATT method	(acofilcon A) - 25.50 (acofilcon B) - 15.8 (tetrafilcon A) - 9.3	(hioxifilcon A) - 25.50	(hioxifilcon A) - 25.50 (hioxifilcon B) - 15.0
d.	Light Transmittance	(acofilcon A) - >93% (acofilcon B) - >94.8% (tetrafilcon A) - > 93%	(hioxifilcon A) >95%	(hioxifilcon A) >95% (hioxifilcon B) >95%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 1 2003

Metro Optics of Autin, Ltd.
c/o Deanna Werber
Medvice Consulting, Inc.
623 Glacier Drive
Grand Junction, CO 81503

Re: K031532
Trade/Device Name: SatureEyes II (acofilcon A), (acofilcon B) & (tetrafilcon A) Soft Contact Lens for Daily Wear (clear and blue visibility-handling tint lathe-cut)
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: May 12, 2003
Received: May 15, 2003

Dear Ms. Werber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Device Name: SatureEyes II (acofilcon A), (acofilcon B) & (tetrafilcon A) Soft Contact Lenses for daily wear (clear, blue visibility-handling tint)

INDICATIONS FOR USE:

The **SatureEyes II (acofilcon A), (acofilcon B) & (tetrafilcon A) Spherical** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity.

The **SatureEyes II (acofilcon A), (acofilcon B) & (tetrafilcon A) Toric** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes with myopia or hyperopia and may have astigmatism of 10.00 diopters or less where the astigmatism does not interfere with visual acuity.

The **SatureEyes II (acofilcon A), (acofilcon B) & (tetrafilcon A) Multifocal** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes with myopia or hyperopia and are presbyopic.

The **SatureEyes II (acofilcon A), (acofilcon B) & (tetrafilcon A) Toric Multifocal** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes with myopia or hyperopia, have astigmatism of 10.00 diopters or less and are presbyopic.

Eyecare practitioners may prescribe the lens for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system.

(PLEASE DO OT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) or Over-The-Counter Use ___

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K031532